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Docket No: 05432/100M919-US5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Connie Sanchez *et al.*

Serial No.: 10/644,576

Examiner: Not Yet Assigned

Confirmation No.: 5194

Filed: August 20, 2003

Group Art Unit: Not Yet Assigned

Title: **THE USE OF ENANTIOMERIC PURE CITALOPRAM**

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PETITION TO MAKE SPECIAL UNDER 37 C.F.R. §1.102

Sir:

This is a petition pursuant to 37 C.F.R. §1.102(d) and M.P.E.P.  
§708.02(VIII) to advance the above-identified patent application out of turn for  
examination. This petition is accompanied by a check for \$130.00 to cover the fee  
set forth in 37 C.F.R. §1.17(h).

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**I. Claims Directed to a Single Invention**

It is believed that the claims pending in this application after entry of the January 5, 2004 Preliminary Amendment and the accompanying Second Preliminary Amendment are directed to a single invention. The present application includes one independent claim (claim 20). Claims 21-37 depend from claim 20.

Claim 20 is directed to a method of treating attention deficit hyperactivity disorder in a patient in need thereof by administering to the patient a pharmaceutically effective amount of escitalopram or a pharmaceutically acceptable salt thereof as the sole active ingredient.

If the Examiner determines that all pending claims are not directed to a single invention, applicants will make an election without traverse as a prerequisite to the grant of special status.

**II. Pre-Examination Search**

A pre-examination search was made in International Class A 61K 31/343 by the Swedish Patent Office, as the International Searching Authority for the International counterpart (PCT Application No. PCT/DK02/00281) to this application during the International phase. The International Searching Authority conducted a search of all 19 claims in the International counterpart to the present application (International Publication No. WO 02/087566, Exhibit 1). Claim 5 of International Publication No. WO 02/087566 is directed to the use of a

composition containing escitalopram (with less than 3% w/w of R-citalopram) for the treatment of patients with, *inter alia*, attention deficit hyperactivity disorder.

The International Search Report and the two documents cited therein are attached as Exhibits 2-4, respectively. Additionally, the above-described international search was supplemented by the following search of U.S. patents and published U.S. patent applications:

<b>Date of Search</b>	July 29, 2004
<b>Database</b>	U.S. Patent and Trademark Office Website
<b>Search Queries</b>	1976-present spec/(citalopram or s-citalopram or escitalopram) or (s-citalopram and attention) or (s-citalopram and adhd) or (escitalopram and attention) or (escitalopram and adhd) or (citalopram and attention) or (citalopram and adhd) or (citalopram and enantiomer) or (enantiomer and attention) 1976-present aclm/(s-citalopram or citalopram)

The above search uncovered one additional reference, namely, U.S. Patent Publication No. 2002/0103249 (Exhibit 5). Below is a discussion of the references cited in the International Search Report and the supplemental search, demonstrating how the claimed invention is patentable over each of the references.

### **III. Discussion of References**

#### **A. EP 347066 A1 ("EP '066") (Exhibit 3)**

The U.S. counterpart to EP 347066 A1 is U.S. Patent No. Re. 34,712, which is a reissue of U.S. Patent No. 4,593,590.

EP '066 discloses the (+)-enantiomer of citalopram, and its use as an anti-depressant. See abstract. EP '066 is completely silent with respect to the use of the (S)-(+)-isomer of citalopram (i.e., escitalopram), or a salt thereof, to treat patients with attention deficit hyperactivity disorder.

Therefore, EP '066 does not disclose or suggest the method recited in the pending claims. Accordingly, claims 20-37 are patentable over EP '066.

**B. WO 01/03694 ("WO '694") (Exhibit 4)**

WO '694 is directed to the use of escitalopram, and its salts, in the treatment of neurotic disorders, such as generalized anxiety disorder, social anxiety disorder, post traumatic stress disorder, obsessive compulsive disorder, and panic attacks. See abstract.

WO '694 does not disclose or suggest the use of escitalopram to treat patients suffering from attention deficit hyperactivity disorder.

Claims 20-37 are therefore patentable over WO '694.

**C. US 2002/0103249 ("US '249") (Exhibit 5)**

US '249 is directed to the use of irindalone in combination with a selective serotonin reuptake inhibitor (SRI) or any other compound, which causes an elevation in the level of extracellular serotonin, for the treatment of depression and other affective disorders. See page 1, ¶ 1. US '249 states:

[T]he present invention relates to the use ... of irindalone ... for the treatment of depression, anxiety disorders and other affective

disorders, eating disorders such as bulimia, anorexia and obesity, phobias, dysthymia, premenstrual syndrome, cognitive disorders, impulse control disorders, attention deficit hyperactivity disorder and drug abuse, in particular depression with a serotonin reuptake inhibitor or any other compound, which causes an elevation in the level of extracellular serotonin.

See pages 1-2, ¶ 17. US '249 further states:

SRIs, which are particularly preferred according to the present invention, include citalopram, escitalopram, fluoxetine, sertraline, paroxetine, fluvoxamine, venlafaxine, dapoxetine, nefazodone, imipramin, femoxetine and clomipramine.

See page 3, ¶ 46. According to US '249, it was surprisingly found that irindalone may be used to augment and provide faster onset of the therapeutic effect of SRIs.

See page 1, ¶ 11.

US '249 does not disclose or suggest the use of escitalopram as the sole active ingredient to treat patients suffering from attention deficit hyperactivity disorder.

US '249 is a reference to the present application under 35 U.S.C. §102(e). Because US '249 and the present application were, at the time the invention claimed in the present application was made, owned by H. Lundbeck A/S or subject to an obligation of assignment to H. Lundbeck A/S, US '249 is not prior art for purposes of obviousness to the present application (35 U.S.C. §103(c)). The present application is assigned to H. Lundbeck A/S at reel 014703, frame 0873. US '249 is assigned to H. Lundbeck A/S at reel 011536, frame 0300.

Claims 20-37 are therefore patentable over US '249.

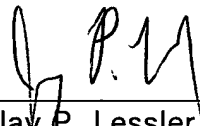
**III. Conclusion**

In view of the foregoing, the PTO is requested to make this application special and to accelerate examination pursuant to 37 C.F.R. § 1.102(d) and M.P.E.P. §708.02(VIII).

Favorable action is earnestly solicited.

Respectfully submitted,

Dated: August 5, 2004

  
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